

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty) (PCT Article 36 and Rule 70)

REC'D 24 JUN 2005

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| Applicant's or agent's file reference W1764-000000 | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
| International application No. PCT/JP2004/010546 | International filing date (day/month/year) 16.07.2004 | Priority date (day/month/year) 17.07.2003 |
| International Patent Classification (IPC) or national classification and IPC Int.Cl. ⁷ A61K31/4439, A61P1/00, 29/00 //C07D417/04 | | |
| Applicant OTSUKA PHARMACEUTICAL CO., LTD. | | |

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|----|---|
| 1. | This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. |
| 2. | This REPORT consists of a total of <u>4</u> sheets, including this cover sheet. |
| 3. | This report is also accompanied by ANNEXES, comprising: <div style="margin-left: 20px;"> a. <input type="checkbox"/> a total of _____ sheets, as follows: <div style="margin-left: 20px;"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. </div> </div> <div style="margin-left: 20px;"> b. <input type="checkbox"/> a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). </div> |
| 4. | This report contains indications relating to the following items: <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application </div> |

| | | |
|---|---|---------|
| Date of submission of the demand 28.12.2004 | Date of completion of this report 13.06.2005 | |
| Name and mailing address of the IPEA/JP Japan Patent Office 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan | Authorized officer SATOSHI YASUKAWA | 4C 3039 |
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010546

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010546

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 4, 5

because:

☒ the said international application, or the said claims Nos. 4, 5
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter of claims 4 and 5 relates to a method for treatment of the human or animal body by therapy, which does not require an intentional preliminary examination by an International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and Rule 67.1(iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 4, 5

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

| | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |

☐ the tables related to the nucleotide and/or amino acid sequence listing do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions in that the computer readable form:

☐ has not been furnished
☐ does not comply with the technical requirements

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/010546

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|-----------|-----|
| Novelty (N) | Claims | _____ | YES |
| | Claims | 1-3, 6, 7 | NO |
| Inventive step (IS) | Claims | _____ | YES |
| | Claims | 1-3, 6, 7 | NO |
| Industrial applicability (IA) | Claims | 1-3, 6, 7 | YES |
| | Claims | _____ | NO |

2. Citations and explanations(Rule 70.7)

D1 BANAN, A. et al, OPC-compounds prevent oxidant-induced carbonylation and depolymerization of the F-actin cytoskeleton and intestinal barrier hyperpermeability, Free Radical Biology & Medicine, 2001, Vol.30, No.3, p.287-298

claims 1-3, 6 and 7

The subject matter of claims 1-3, 6 and 7 neither appear to be novel nor to involve an inventive step in view of the Document 1 cited in the ISR.

Document 1 discloses that OPC-6535 (6-[2-(3,4-diethoxyphenyl)thiazol-4-yl]pyridine-2-carboxylic acid) may be used as a novel therapeutic agent for treatment of a variety of oxidative inflammatory intestinal disorders such as inflammatory bowel disease (see abstract), and Document 1 also discloses that enema administration of OPC compound could effectively scavenge oxidants (see p.296 right column).

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